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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/720,513      | 03/26/2001  | Therese Jourdiar     | MBHB00-1282         | 3546             |

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EXAMINER

LI, BAO Q

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/720,513             | JOURDIER ET AL.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Bao Qun Li             | 1648                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

Claims 10-15 are pending.

#### ***RCE***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/29/2004 has been entered. The RCE action follows:

#### ***Declaration under 37 C.F.R. 1.132***

1. The Declaration by Dr. Therese-Marie Jourdier under 37 CFR 1.132 filed October 29, 2003 has been acknowledged. However, it is insufficient to overcome the rejection of claims 10-15 based upon Obvious Rejection as set forth in the last Office action.

#### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 10-15 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Carrano et al. (WO 95/26718A1), Groswasser et al. (Pediatrics 1997, Vol. 100, page 400-403), Stites et al. (Medical Immunology edited by Stites et al. 1997, pages 782, Appleton & Lange, Stamford, Connecticut) and Bouvet et al. (Infect. Immun. 1994, Vol. 62, pp. 3957-3961).

4. In response to the Office Action, Applicants filed a declaration under 1.132. in the declaration, Dr. Jourdier stated that the anti-gp160 IgG + B lymphocytes observed in the internal and external iliac lymph nodes and inguinal lymph node ranged from 18 to 350 times than in the submaxillary and axillary nodes and in the blood. Applicants further argue that because the rectogenitourinary lymph node system and mucous membrane is highly complex and integrated, one of ordinary skill in the art would understand that an immune response similar to that observes internal and external iliac lymph nodes and inguinal lymph nodes would be present in other lymph nodes of the rectogenitourinary system.

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5. The argument has been fully considered; however it is not persuasive because it does not state that the data presented on page 19 does not have a control group. Therefore, it cannot conclude that claimed subject matter solved a problem that was long standing in the art and it is an unexpected result.

6. In the previous Office Action, Office states that Carrano et al. disclose method of immunization of human being comprises introduction of a genetic construct into an individual by intramuscularly or skin injection. It is well known that the common sites for the intramuscular injection of vaccine are either at the arm or thigh. A better immune response has been reported with intramuscularly injection at the thigh of leg, particularly with the quadriceps as evidenced by Groswasser et al. (Pediatrics 1997, Vol. 100, page 400-403) and Stites et al. (Medical Immunology edited by Stites et al. 1997, pages 782, Appleton & Lange, Stamford, Connecticut). Stites et al. teach that recent studies of injection techniques suggest that the anterolateral thigh or deltoid site is preferable to the buttocks. Groswasser et al. disclose that a better immune response for intramuscular compared with subcutaneous injection has been seen with several vaccines, such as the hepatitis B, rabies and influenza vaccines (See first paragraph on page 400), wherein the thigh injection referred by Dr. Groswasser et al. is the site of quadriceps (See section of materials and methods on page 401). Bouvet et al. teach that the possibility of inducing protective antibodies by development of true secretory vaccine seems to be of major interest because the antibodies in secretions can play a key role against the pathogens, which remain in the genital area.

7. Therefore, Office concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention was filled to be motivated by the teaching of Bouvet et al. to use the parenteral immunization strategy taught by Groswasser et al. and Stites et al. for immunizing human with the vaccine compositions as disclosed by Carrano et al. to protect the sexual transmitted diseases, such as HIV, HPV, HSV and others because the intramuscular systemic immunization can induce a same increase of local antibodies secreted from the mucosal and congenital routes, which may provide a local immune defense against the entry of the sexual transmitted pathogens. As there are no unexpected results have been provided, such as the thigh quadriceps injection of an antigen is able to get a significant higher local antibody response

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compared with the antibody induced by injecting same amount of said antigen in other muscles of the body, the claimed invention as a whole is prima facie obvious absence unexpected results.

8. In addition, the declaration and applicants' argument have not shown that others of ordinary skill in the art were working on the problem and if so, for how long. In addition, there is no evidence that if persons skilled in the art who were presumably working on the problem knew of the teachings of the above cited references; they would still be unable to solve the problem. See MPEP § 716.04.

9. Since there is no unexpected result, the rejection is still maintained.

### ***Conclusion***

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li

April 1, 2004

  
JAMES HOUSEL 4/2/04  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600